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Community case management and unplanned hospital admissions in patients with heart failure: a systematic review and qualitative evidence synthesis.

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Impact Statement

Heart failure (HF) is a common condition in the over 70s population. Research often focuses on secondary care, yet much of the care for people with HF is community-based. This research contributes towards our understanding of best care practice in the community.

Unplanned and potentially unnecessary hospital admissions in the older population is a growing problem. These admissions are costly and not always in the best interest of patients. Whilst this qualitative synthesis cannot provide a causal link between case management of people with HF and reducing hospital admissions, it does provide explanatory evidence to complement promising clinical trial data.

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Abstract

Aims

To describe case management as experienced by patients with heart failure and their health professionals with the aim of understanding why case management might contribute in reducing hospital admissions.

Background

Heart failure is a common cause of unplanned hospital admission. The evidence for case management in patients with heart failure for reducing admissions is promising.

Design

Systematic review and qualitative evidence synthesis.

Data source

Searches were conducted in Medline, Psychinfo, Kings Fund database and Cinahl from inception of each database to February 16th 2017.

Review methods

Robust systematic review methodology was used to identify qualitative studies describing the experiences of patients with heart failure and health care providers of case management. Data were synthesised thematically and analytic themes were developed.

Results

Five studies (six papers) from which nine descriptive themes were used to determine three analytic themes. This synthesis showed that case management provides positive quality of care for patients, increases perceived access to services, and creates more time in which to ask questions and develop trusted relationships. For health professionals, case management enhanced care by improved relationships with both patients and colleagues although concerns remained around resources, training and inter-professional conflict.

Conclusions

This synthesis emphasises the importance of the quality of being cared for as a patient and caring as a health professional. Case management enhances communication between patients and health professionals, supports patient self-care and self-management, and can be an important contributing factor in reducing unplanned admissions for patients with heart failure.

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Key words systematic review, qualitative evidence synthesis, heart failure, nursing, case management, hospital admission, primary care, thematic synthesis

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SUMMARY STATEMENT

Why is this research needed?

- Approximately 1–2% of the adult population in developed countries has heart failure, with the prevalence rising to ≥10% among persons ≥70 years of age.
- A recent systematic review found that hospital–initiated case management continuing into the community can reduce subsequent unplanned hospital admissions and hospital length of stay for heart failure patients, although cost-effectiveness data is lacking.
- Case management is usually coordinated by a heart failure nurse and is defined as ‘A collaborative process of assessment, planning, facilitation, care coordination, evaluation, to meet an individual’s and family’s comprehensive health needs.’

What are the key findings?

- This synthesis showed that case management provides positive quality of care for patients, increases perceived

access to services, and creates more time for patients to ask questions of health professionals and develop trusted relationships.

- For health professionals, case management enhanced care by improved relationships with both patients and colleagues although concerns remained around resources, training and inter-professional relationships.

How should the findings be used to influence policy/practice/research/education?

- This synthesis of the experience of case management of heart failure patients and their health professionals emphasised the importance of quality in being cared for as a patient and caring as a health professional. This evidence should be used in nurse training on case management for heart failure.
- Case management enhances communication between patients and health professionals, supports patient self-care and self-management, and is a contributing factor in reducing unplanned admissions for heart failure patients. Increased availability of case management is recommended for patients with the caveat that increased attention to professional role boundaries should be included.

Introduction

Recent research has concluded that hospital-initiated case management continuing into the community can reduce subsequent unplanned hospital admissions and hospital length of stay for patients with HF, although cost-effectiveness data is lacking.

Previous research shows that case management does not reduce unplanned admissions in study populations recruited on older age as opposed to a specific condition or for patients with COPD. (Huntley *et al.* 2013, Purdy 2012) It is likely that case management is particularly beneficial for patients with heart failure by allowing more quality time for focussed and difficult discussions between health professionals and patients around the diagnosis of heart failure and its implications. (Simmonds *et al.* 2015). Case management also provides essential ongoing education and support.

This systematic review and synthesis of qualitative studies of the experiences of case management for patients with heart failure and relevant health professionals was conducted and used to explore how case management might reduce unplanned hospital care.

Background

Approximately 1–2% of the adult population in developed countries has heart failure (HF), with the prevalence rising to $\geq 10\%$ among persons ≥ 70 years of age. (Mosterd 2007) Since the early nineties, effective treatment has improved outcomes for people with HF, with a reduction in hospitalisation and smaller but significant decrease in mortality. (Stewart *et al.* 2001, Stewart *et al.* 2010, Jhnund *et al.* 2009)

Case management is usually coordinated by a heart failure nurse and is defined by the King's Fund in the United Kingdom as 'A collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality cost-effective outcomes.' (Ross *et al.* 2011).

The Review

Aims

The aims of this qualitative synthesis were to understand the context in which case management is delivered from the patient and health professional viewpoint, and the contribution case management may have in reducing unplanned admissions.

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Specifically: a) which patient-related experiences and activities during case management are likely to help to reduce admissions; and b) which case management professional-related experiences and activities are likely to reduce admissions.

Design

This was a systematic review that included a qualitative evidence synthesis. (Higgins, 2011) (Thomas *et al.*2008)

Search methods

A search strategy was developed (see Appendix 1), searches were conducted in Medline, Medline in Process, Psycinfo, the Kings Fund database and Cinahl from inception of each database to July 2014. These searches were updated February 16th, 2017.

Search outcome

Our inclusion criteria were qualitative studies of patients with heart failure and case management written in any language. Reviewers hand searched the references of full text papers and key authors were contacted. Studies that did not use standard qualitative methodology were excluded. Two reviewers screened references by title and abstract and disagreements were resolved by discussion with another member of the team.

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Quality appraisal

The papers were assessed using the **Critical Appraisal Skills Programme checklist**. (CASP 2014) This **process** was conducted independently by two reviewers with any differences discussed.

Data abstraction

The demographics of the included studies were first extracted into narrative table; then in line with Thomas and Harden's approach, study findings (data) were extracted into a custom designed word table, by two reviewers independently (AK, RJ, HC, AH). Data relevant to the research question was extracted as participant quotes, or as themes described by the authors of the original papers.

Synthesis

Data were extracted and analysed following Thomas and Harden's description of thematic synthesis. (Thomas *et al.* 2008) 'Thematic synthesis has three stages: the coding of text line-by-line; the development of 'descriptive themes'; and the generation of 'analytical themes'.

In the first stage of synthesis (coding), the lead reviewer (AK) collated the findings focusing mainly on the original authors themes

as the primary data (and quotes) tended to be illustrative and not substantial. The review team (AK, RJ, HC, AH) then met face to face to review and agree a coding framework and discuss how any primary data (quotes) that were available mapped to these newly synthesised themes (to facilitate the writing up process). In the second stage the review team met to further discuss, translate and consolidate the initial themes to produce descriptive themes. As discussed by Thomas and Harden, these descriptive themes are still closely related to the findings of the original studies. The final stage was to discuss and determine the analytic themes that adequately represented a synthesis of the core findings; this was achieved through face to face meetings and by email correspondence. These analytic themes are representative of the review team's inferences of the themes developed by primary studies with regard to case management for patients with heart failure.

Results

Six papers describing five studies of case management of heart failure were included. (Figure 1: PRISMA diagram) These studies described case management including a nurse-led heart failure clinic in the community, case management within general practice run by nurses, case management in long-term residential care for older

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people and case management at home. (Young *et al.* 2007, Nasstrom *et al.* 2015, Lloyd-Williams *et al.* 2005, Close *et al.* 2013, Peters-Klimm *et al.* 2009, Olbort *et al.* 2009) (Table 1) (Appendix

three)

The papers were assessed using the CASP checklist; overall quality was satisfactory for all included studies (Appendix 2) (CASP 2014)

Where relevant study limitations are discussed with the appropriate section of the results. There were some issues of population

sampling (Young *et al.* 2007, Close *et al.* 2013) and appropriate involvement of study personnel. (Peters-Klimm *et al.* 2009, Olbort *et al.* 2009). Only one study described the relationship between researcher and the participants (Close *et al.* 2013)

Descriptive and analytic themes (Figure 2)

Nine descriptive themes were developed by the authors from the primary papers. Three themes were derived from the experiences of patients, three themes were derived from the experiences of both patients and health professionals and three themes relate to the experiences of health professionals. (Table 2) Three analytic themes were identified: increased connection to care for patients; enhanced experience of care for patients; and enhanced care provision for

health professionals. These analytic themes were used as a framework for our discussion.

Patient themes

Checking on/being cared for (Young *et al.* 2007, Nasstrom *et al.* 2015, Lloyd-Williams *et al.* 2005, Close *et al.* 2013).

The studies highlight the importance of case management especially the work of heart failure nurses doing a physical assessment, monitoring and inquiring about patients’ self-care outside the formal care setting. The study by Young in which patients were cared for in their own home by nurses describes that patients valued the ‘checking on’ aspect of case management and felt it helped them remain at home and manage their illness. (Young *et al.* 2007). In this study the five patients were recruited from various inpatient and outpatient facilities with heart failure of differing severity and are likely to have varied care needs which are not explicit in the patients’ quotes. Patients described how they felt cared for when heart failure nurses checked up on them as part of case management. They felt a sense of ‘being connected’ to their care.

This theme was also apparent in the Nasstrom and the Close study in which patients lived in sheltered /residential care respectively. (Nasstrom *et al.* 2015, Close *et al.* 2013) This patient response does

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not seem to be location specific as this theme was also identified in the Lloyd Williams study in which people attended a primary health care practice. One participant commented:

“I think you felt that you were being looked after, you know, you didn’t feel as though you were being neglected in any way. You felt as if somebody cared about you, and I think that’s a big deal really”. (Patient 15, Lloyd-Williams *et al.* 2005)

Changes in behaviour (Nasstrom *et al.* 2015, Lloyd-Williams *et al.* 2005).

Case management was thought to help patients make lifestyle changes, know when to access their healthcare team, self-monitor and support changes in health behaviour. Case management helped increase patient awareness of heart failure which meant they were more reassured and more likely to make lifestyle changes including diet and exercise.

“...I like Chinese foods and there’s quite a bit in that and I used to like to have a drink of Bovril....I haven’t stopped taking them, but less frequent...”. (Patient 12, Lloyd-Williams *et al.* 2005)

Whilst this theme was only present in two of the papers, these studies were carried out in two contrasting settings; the patient's own home with one nurse and in a residential home setting which provides nurse support within a multidisciplinary team.

What is important to patients? (Nasstrom *et al.* 2015, Close *et al.* 2013)

Being able to stay at home and receive care was of significant value to patients receiving case management in two of the studies based in sheltered/ residential care. This included patients wanting to avoid hospital admission. In the study by Close where participants were already living in care homes, the author commented that "Participants seemed to equate hospitals with danger zones, where the potential for illness was everywhere.... Moreover; patients felt that health and happiness were more easily achievable in the familiar setting of one's home". (Close *et al.* 2013)

Importantly, participants in the Close study were recruited from 33 homes which are likely to have varied in terms of facilities and population. Some participants stressed that they were happier at home and this would positively contribute towards their health and their ability to get on with their daily lives and routines whether that was getting to the hairdressers or just doing things for themselves.

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“I mean I go to the hairdressers once a fortnight now...I got that I wasn't able to go at all...and even the hairdresser says 'you've improved a lot'”. (Resident 11, Close *et al.* 2013)

Patient & health professional themes

Information & education (Young *et al.* 2007, Nasstrom *et al.* 2015, Lloyd-Williams *et al.* 2005, Close *et al.* 2013, Peters-Klimm *et al.* 2009)

In the absence of case management, it was thought that the main issues arising were patients not understanding their heart failure diagnosis; why nurses were doing particular health checks; why they should take medication; and finding it hard to adhere to advice or retain information given by health professionals. All the studies made a direct link between how much information patients received, its quality, context and their perception of participation in care decision-making, all of which were more likely to occur with case management. In terms of health professionals' views of the impact of case management on patients this was seen mainly in terms of increasing patient knowledge of heart failure and improving self-management. (Lloyd-Williams *et al.* 2005, Peters-Klimm *et al.* 2009, Olbort *et al.* 2009) When asked what the most important feature of care was for heart failure patients one nurse said:

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6 “Education probably knowledge; they are aware of their own
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8 symptoms and they know when to seek help”. (Nurse 3, Lloyd-
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10 Williams *et al.* 2005)
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14 The lack of patient understanding about medication was emphasised
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16 by health professionals referring to patients who had previously not
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18 attended a nurse-led heart failure clinic. (Lloyd-Williams *et al.* 2005).
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23 “Well I keep taking the tablets at the end of the day but I haven’t a
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25 clue what they’re for”. (Resident 7, Close *et al.* 2013)
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29 Lloyd-Williams states that when health professionals explained to
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31 patients why a medication had been prescribed and how it controlled
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33 heart failure it was also thought to increase patient compliance.
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36 This fits very well with the broader interventional evidence for
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38 educational/informational approaches having a positive relationship
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40 with reduction of unplanned admissions. (Purdy 2012)
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“You feel that it really appeals to the patients. They can now talk quite a bit more than usual when they visit the practice”. (Doctors’ assistant, Olbort *et al.* 2009)

Self-management and self-care (Young *et al.* 2007, Nasstrom *et al.* 2015, Lloyd-Williams *et al.* 2005, Peters-Klimm *et al.* 2009, Olbort *et al.* 2009).

Self-management is a term used to include all the actions taken by people to recognise, treat and manage their own health. They may do this independently or in partnership with the healthcare system. (NHS England (a)) Whereas self-care is the actions that individuals take for themselves, on behalf of and with others to develop, protect, maintain and improve their health, wellbeing or wellness. (Self-care forum)

Patients in the included studies described the reassurance that case management and nurse-led heart failure care gave, and this supports both self-care and self-management. It is not always possible to distinguish between these activities in the included studies.

This is also related to raising patient awareness of heart failure, the need to have knowledge about their heart failure management

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reinforced and having someone who was interested in their condition. Patients emphasised the nurse’s role in patient self-care/self-management.

“I’ve got to weigh myself every morning when I get out of bed. That was one of the things she told us we can check. Increasing of weight and ankle swelling and quite honestly I’ve never known my legs to be so thin. If I got a quick two-pound difference I’d let them know straight away”. (Patient 9, Lloyd-Williams *et al.* 2005)

In examining the impact of case management on self-management Lloyd-Williams stated that “the nurses felt that the information provided at the clinics had enabled patients to develop a better understanding of their condition and consequently enabled them to manage their illness and feel empowered about their condition”. (Lloyd-Williams *et al.* 2005) One nurse in the same study commented that prior to implementing case management patients had not received information on basic self-care such as making dietary changes. (Lloyd-Williams *et al.* 2005)

Olbort describes how case management affected the health professional/patient relationship and the positive impact of this on

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self-management. (Olbort *et al.* 2009) The following health professional quote also relates back to the theme of changing behaviours.

“Many [patients] also want to show what they do. One of my patients showed me his brand new fitness bike in order to show me his activities and said he uses it in the morning in front of the TV”.
(Doctors’ assistant, Olbort *et al.* 2009)

Enhanced access to care (Young *et al.* 2007, Nasstrom *et al.* 2015, Lloyd-Williams *et al.* 2005, Peters-Klimm *et al.* 2009, Olbort *et al.* 2009).

Case management was perceived by patients to enhance access to care overall. Heart failure was seen as a complex condition and the availability of information needed to be an ongoing process in order to achieve a good understanding for most patients (Nasstrom *et al.* 2010). Patients emphasised the impact of case management on quality of care was the timeliness of being able to access the heart failure specialist nurse, the reliability of this service and being able to develop a trustful relationship. It was also the context within which this relationship developed and patients’ perception that this was their “protected time”. (Lloyd-Williams *et al.* 2005).

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6 “Yes, if I am beginning to feel really bad...then I get in touch with
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8 them.. and they get in touch with her (the visiting nurse), and then
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10 she...calls me”. (Patient 18, Young *et al.* 2007)
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15 “This provided an opportunity to manage the situation from a more
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17 holistic perspective, rather than the fragmented approach that was
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19 experienced with other forms of health-care contact”. (Nasstrom *et al.*
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21 2015).
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25 Home visits which often accompanied case management were
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27 perceived by patients to be less time pressured and thus enabled
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29 patients to ask questions that were important to them.
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34 “You can talk with them. It is easier than if you have to call the
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36 doctor and talk, then you always have to hurry, it is not really the
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38 same but they are never in a hurry in that way...they are never
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40 stressed really but they can sit there and have a minute of peace and
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42 quiet”. (Patient 5, Nasstrom *et al.* 2013)
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47 Young argues that with case management the heart failure nurses
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49 act as an advocate for patients living in their own homes enabling
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4 them to stay well. He emphasises the importance of other patient
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6 resources as part of this including: financial resources; strong
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8 community relationships and relationships with other community
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10 health care services; and patients' families and carers. What was
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12 also important to patients was that case management could be
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14 patient-initiated. (Young *et al.* 2007)
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19 In addition, case management was also seen to enable health
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21 professionals to develop a more patient-focused approach to heart
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23 failure care. (Peters-Klimm *et al.* 2009)
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28 **Health professional themes** (Peters-Klimm *et al.* 2009, Olbort *et al.*
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30 2009, Close *et al.* 2013).
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32 The health professional themes come predominantly from one study
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34 of case management in primary care facilitated by nurses (described
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36 as doctors' assistants in paper) and GPs. (Peters-Klimm *et al.* 2009,
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38 Olbort *et al.* 2009). It is also important to point out that four of the
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40 five focus groups in these two studies were co-run by the principal
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42 investigator (a general practitioner) and the remaining one was run
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44 by a research nurse, both of which could influence the findings and
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46 direction of the discussion.
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The study by Close also provides an important angle on the role of case management in the care home setting as it is the only study that participants are not living independently in a domestic setting (Close *et al.* 2013).

Feasibility of case management (Peters-Klimm *et al.* 2009, Olbort *et al.* 2009, Close *et al.* 2013)

Doctors in the primary care setting study were positive about case management overall and viewed the implementation of case management for heart failure from the perspective of how it affected their 'normal' commitments and workload. (Peters-Klimm *et al.* 2009) However, the views of the nurses were more mixed and for some case management obviously put a lot of pressure on them.

"I practically do it during my time off. I work part-time 20-24 hours a week, always in the afternoon – and the first home visit was on a Monday... the day started at 8am and went until 10.30 or 10.45. That's how long I was busy then". (Doctor's assistant 24, Olbort *et al.* 2009)

Not all doctors viewed the implementation of case management positively either. This related partly to doctors' perception of the

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value of aspects that could be included in case management for different types of patients. (Peters-Klimm *et al.* 2009)

“In the end, maybe also due to my type of patients, patients and I had no benefit [of the telephone monitoring]. All-in-all, it stayed the way it was”. (Doctor R, Peters-Klimm *et al.* 2009)

In the Close study based in a care home, no one taking overall responsibility of resident's health care was a strong theme and this was reflected in the heart failure nurses' experiences who were providing case management to this population.

“It probably sounds silly but, you know, you do feel like it's somebody else's responsibility and you're dipping into it really.” (HFN2, Close *et al.* 2013)

Suggestions for improvements (Peters-Klimm *et al.* 2009).

GPs suggested that explaining the benefits of case management in primary care should be part of nurse's training. Other suggestions included the need to implement patients' medication review into the therapy planning by GPs. Some GPs stated that the financial issues in implementing case management and its impact on professional

roles needed examining. It was suggested that extra remuneration of doctors' assistants for performing case management roles should be provided. (Peters-Klimm *et al.* 2009).

Health professional roles and relationships (Peters-Klimm *et al.* 2009, Olbort *et al.* 2009).

Case management overall was seen as having a positive effect on professional roles and relationships. The authors reported that "This enhanced role and working together with patients was seen by most doctors' assistants as a positive shared effect of case management". (Olbort *et al.* 2009).

The nurse's experiences with their relationships with GPs were more mixed. Most nurses reported that feedback received from GPs about their case management reports was valued and showed the shared nature of the management process but not all comments were positive.

"He [the GP] then includes me afterwards, regarding the changes or consequences of it [the monitoring]. Or if he adds some new medications". (Doctors assistant 13, Olbort *et al.* 2009)

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The majority of nurses reported developing greater understanding of patients' backgrounds and psychological wellbeing, in terms of patients' social environments. (Olbert *et al.* 2009)

They talked about their enhanced relationship with the patients.

These had become closer, more intensive and involved more contact, resulting in more personal relationships.

Discussion

The aim of this systematic review and qualitative evidence synthesis was to examine the patient and health professional viewpoints of case management and use this to explore the mechanisms as to how case management might reduce unplanned hospital care. A recent systematic review has concluded that hospital-initiated case management continuing in the community for patients with heart failure can reduce subsequent unplanned admissions and hospital length of stay. [REDACTED]

In the present review, the descriptive themes tell us that it is important to patients with heart failure that they remain at home and get on with their normal lives and activities, and case management facilitates this. Admission to hospital is perceived negatively.

Three analytic themes were identified: increased connection to care for patients; enhanced experience of care for patients; and enhanced care provision for health professionals. Two of the analytic themes relate to patients and show that with case management patients has **increased connection to their care** in terms of understanding their care. Greater understanding of care leads to increased self-management and self-care behaviours. Patient have an **enhanced experience of care with** perceived enhanced access to services; care in their own home; more time and better quality communication with health professionals. All these factors derived from the qualitative **evidence** synthesis suggest that case management provides heart failure patients with a higher quality of care experience compared to usual primary health care and that this is very important to patients. This conclusion dovetails with the results of a recent realist review which aimed to identify the main mechanisms of heart failure disease management programmes in all settings. The main mechanisms identified in this review were associated with increased patient understanding of heart failure and its links to self-care, greater involvement of other people in this self-care, increased psychosocial wellbeing and support from health professionals to use technology. (Clark *et al* 2016)

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Quality of care can be defined in different ways. NHS England has a useful definition, describing three dimensions of quality of care which all need to be present: Care that is clinically effective, not just in the eyes of clinicians but in the eyes of patients themselves, care that is safe and care that provides as positive an experience for patients as possible. (NHS England (b)) This definition supports our patient-centred interpretation of quality of care.

Extending the argument that if patients with heart failure receive higher quality of care because of case management and that it may contribute its success in reducing hospital admissions we look to the published literature.

Previous research showed that most case management interventions involve monitoring signs and symptoms (disease management) and education or information. [REDACTED] These approaches are thought to be key to reducing admissions. (Jovicic *et al.* 2006, Ditewig *et al.* 2010, Boren *et al.* 2009). However, few case management for heart failure trials focused on the mechanisms for the better monitoring of signs and symptoms, although a minority describe components such as patient directed access, referral to other services, assessment of home environment and emotional support. [REDACTED]

Another recent systematic review reported that being able to see the same healthcare professional (continuity of care) reduced unscheduled secondary care. Better access was also associated with reduced unscheduled care. However, evidence relating to quality of care as measured by indicators was limited and mixed. (Huntley *et al.* 2013)

A UK ethnographic study across primary, community and secondary care of patients with heart failure concluded that fragmented healthcare and discontinuity of care added complexity and increased the likelihood of suboptimal management and unplanned admissions. (Simmonds *et al.* 2015)

Our qualitative synthesis shows that case management is likely to support greater continuity of care as well as less fragmented and more holistic care, with patients experiencing or having the perception of better access to care. We propose that case management can contribute to reducing admissions via improving continuity and increased access to health professionals.

The third overarching theme showed that case management facilitated enhanced care provision for health professionals in terms of having more time with patients, better understanding and

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better quality communication with both patients and colleagues.

However, reservations were voiced by health professionals about training and staffing resources. This highlights an important caveat of the [REDACTED] which showed that, despite a positive effect of case management on subsequent admission, the cost-benefit of case management was undetermined with little data on intervention/admission costs, and no cost information on staffing resources or training. In addition, two of the five studies described inter-professional working; both the German study (Peters-Klimm *et al.* 2009, Olbort *et al.* 2009) and the UK study in care homes (Close *et al.* 2013) discuss conflict between nursing staff and consultant/doctors in delivering case management. These raise issues as to who is ultimately in charge and workload.

The strengths of this systematic review are that it is to our knowledge the first systematic review and qualitative evidence synthesis on case management of heart failure in primary care, including both patient and health professional experience of case management. It uses rigorous systematic review and qualitative evidence synthesis methodology. The limitations of this review are that whilst all the included studies described community-based case management, there was a variety of case management provision and settings, patients had a range of severity of disease and that the views of

health professionals were dominated by one study. (Peters-Klimm *et al.* 2009, Olbort *et al.* 2009). However, the overall quality of the papers was good and contributed significantly to the discussion on case management and heart failure in primary care.

Conclusion

Our qualitative synthesis of patient and health professional experiences of case management **mostly** shows a positive picture. Patients highlight the increased quality of care they received through case management and health professionals describe improvement in both their professional and patient relationships through case management although training and resources and **inter-professional conflict** were a concern. We propose that this improvement in the quality of being cared for and in caring with case management is likely to contribute to reducing unplanned admissions.

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View Copy

Table 1: Study description table

Patient studies n=2				
Author Date Country Setting	Sample size	Patient demographics	Type of case management	Data collection Theoretical approach Data analysis
Young 2006 Canada Community	5 HF patients	Age range 72-97yrs Female: 40% Ethnicity: Jewish(3) Ethiopian(1) plus 1	HF-specific nursing care in the community	Semi-structured interviews. Grounded theory methodology. Content analysis.
Nasstrom 2013 Sweden Home care units	19 HF patients	Age range 63-90yrs Female: 32% Ethnicity: Not stated	HF at Home Model with a multi-disciplinary team	Qualitative interviews Not stated Inductive approach
Patient/HP studies n=2				
Lloyd-Williams 2005 UK Primary care	15 patients & 4 nurses	Age range 60-88yrs Female: 13% Ethnicity: Not stated	Nurse-led HF clinic	Semi-structured interviews Not stated Constant comparative analysis
Close 2013 UK Residential care home	17 patients, 8 care home staff, 5 GPs & 3 HF nurses	Age range 73-94yrs Female: 52% Ethnicity: White British 100%	Tailored, consultant-led management plan delivered by HF nurses.	In-depth interviews Transcendental phenomenology Thematic analysis
HP studies n=2				
Peters-Klimm 2009 Germany Primary care	24 GPs	Age range 33-66yrs Female: 25% Ethnicity: Not stated	Multi-faceted CM approach based in GP practices.	semi-structured focus groups Not stated Inductive content analysis
Olbort 2009 Germany Primary care	27 doctors' assistants (DAs)	Age range 21-54yrs Female:100% Ethnicity: Not stated.	Multi-faceted CM approach based in GP practices.	Four focus groups Not stated Inductive content analysis

Key: CM case management, HF heart failure, HP health professional

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Table 2: descriptive themes (derived by review authors)

Descriptive theme	Primary papers contributing
Patient	
Checking on/being care for	1,2,3 &4
Changes in behaviour	2&3
What is important to patients?	2&4
Patient & Health professional	
Information & education	1,2,3,4 &5
Self-management and self-care	1,2,3,5&6
Enhanced access to care	1,2,4,5&6
Health Professional	
Feasibility of case management	4,5&6
Suggestions for improvement	5
Health professional roles and relationships	5 &6

List of papers

1. Young 2006
2. Nasstrom 2013
3. Lloyd-Williams 2005
4. Close 2013
5. Peters-Klimm 2009
6. Olbort 2009

Figure one: PRISMA Flow Diagram

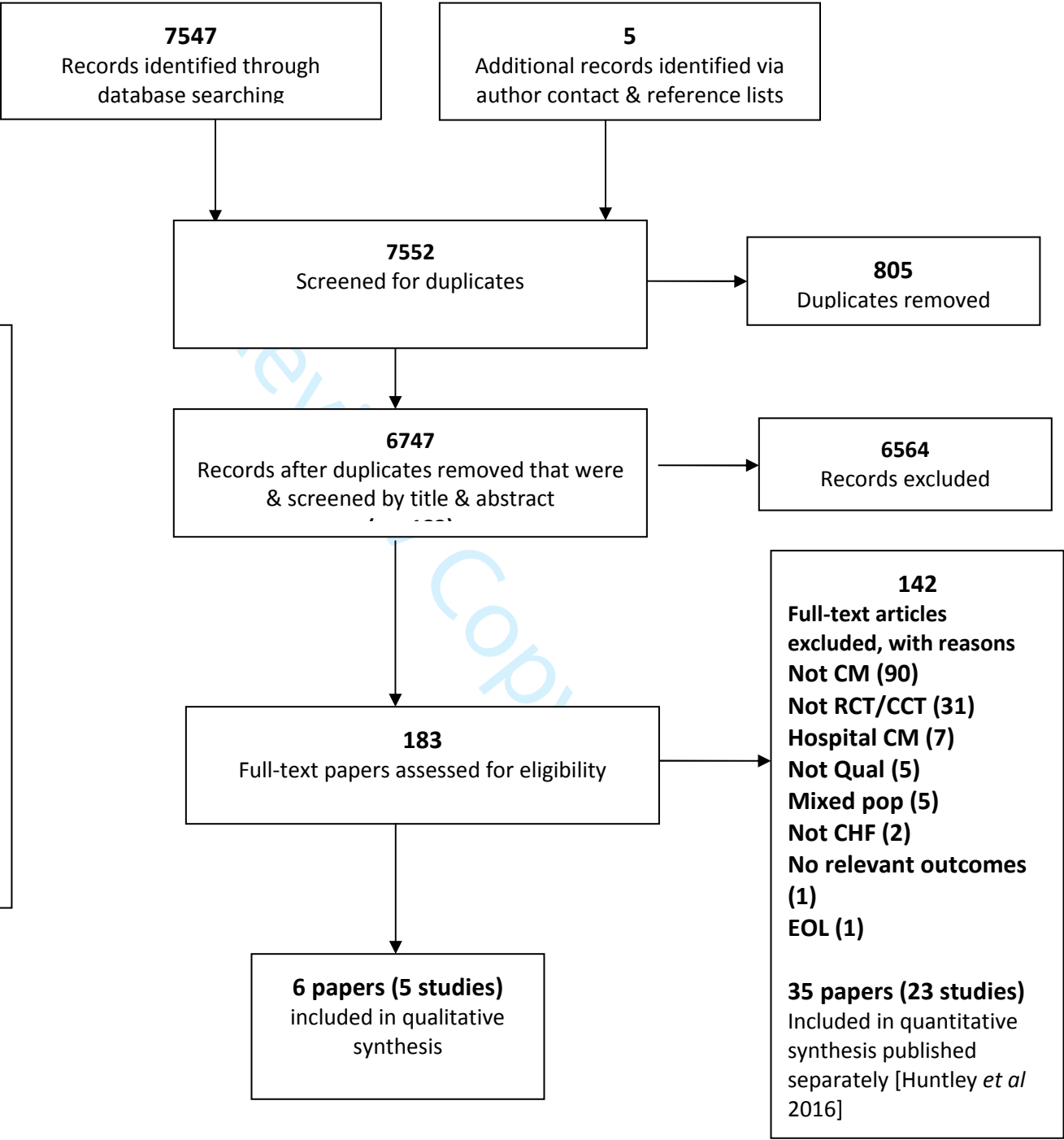
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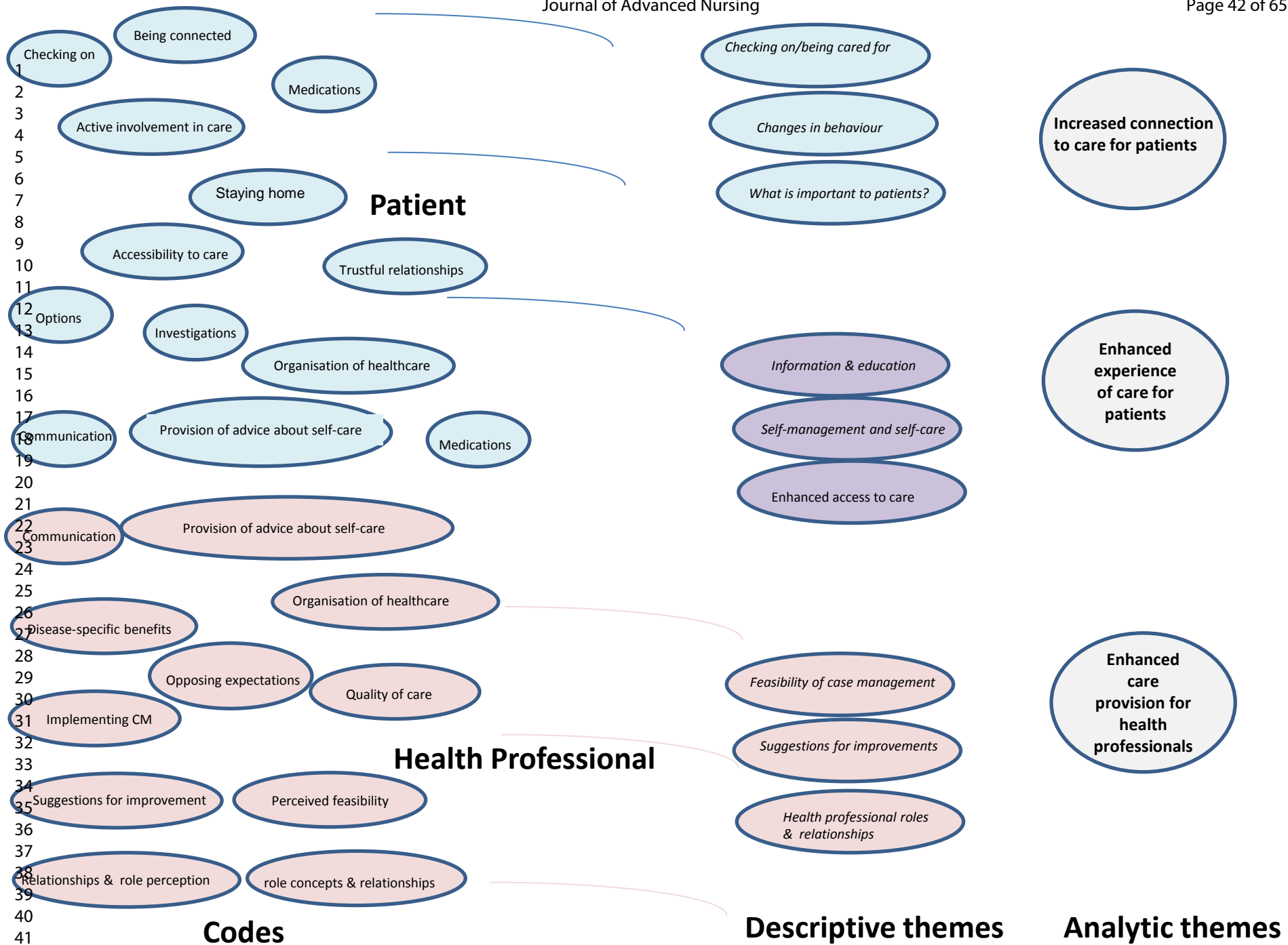
Updated searches
conducted 16.02.17

2304 records after
duplicates removed

22 selected by title
& abstract

5 full papers of
which **4** were
excluded on reading
as intervention was
not CM. The
remaining paper
was a systematic
review and included
in discussion.
[Clarke et al 2016]





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Database: Medline In-process - Current week, Medline 1950 to present
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 - 4 intervention\$.tw. (556397)
 - 5 evaluat\$.tw. (2214967)
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 - 8 semi-structured questionnaire.mp. (1162)
 - 9 observation methods.mp. (152)
 - 10 Observation/mt [Methods] (635)
 - 11 Nvivo.mp. (639)
 - 12 interview/ (25018)
 - 13 Personal Narratives/ (877)
 - 14 Focus Groups/ (16824)
 - 15 patient experience*.mp. (8525)
 - 16 or/7-15 (70071)
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 - 18 exp Heart Failure, Diastolic/ (496)
 - 19 exp heart failure, systolic/ (789)
 - 20 exp Ventricular Dysfunction/ (26332)
 - 21 chronic heart failure.mp. (11341)
 - 22 congestive heart failure.mp. (33082)
 - 23 cardiac failure.mp. (10151)
 - 24 LV dysfunction.mp. (2827)
 - 25 left ventricular dysfunction.mp. (9373)
 - 26 left ventricular impairment.mp. (188)
 - 27 diastolic impairment.mp. (121)
 - 28 systolic impairment.mp. (93)
 - 29 or/17-28 (135885)
 - 30 exp Case Management/ (8326)
 - 31 exp Patient Care Planning/ (52319)
 - 32 organisation of care.mp. (367)
 - 33 community matron.mp. (44)
 - 34 "Continuity of Patient Care"/ (14497)

35 Community Health Nursing/ (18371)
 36 transit* care.mp. (580)
 37 Interdisciplinary Communication/ (10602)
 38 Patient Discharge/ (18977)
 39 discharge plan.mp. (176)
 40 exp Patient Care Management/ (535496)
 41 Comprehensive Health Care/ (6078)
 42 exp Managed Care Programs/ (38918)
 43 Primary Health Care/ (54234)
 44 Community Health Services/ (26923)
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 46 Family Practice/ (60223)
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 48 multidisciplinary.mp. (44988)
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 52 49 and 51 (2590)
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Appendix 2: CASP of included studies

Article and date	Was there a clear statement of the research aims?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Were the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	Limitations	Reference to wider literature	How valuable is the research?
Close 2013	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y Participants both patients and staff were recruited from 33 homes which were likely to vary in terms of facilities and population	Y	Contributes to the field where there is little research – experience of older people with HF in <i>long-term care</i> . Also includes perceptions of GPs, HF nurses = care home staff on HF management.
Peters Klimm 2009	Y	Y	Y	Y	Y	N	Not stated	Y	Y	Y The PI jointly ran 4 of the focus groups (conflict of interest) The fifth was run by a study nurse. Also trial recruited	Y	GPs' perceptions of a case management approach in German general practices. Contributes to paucity of research in this area.

										across urban-rural.		
Olbort 2009	Y	Y	Y	Y	Y	N	Y	Y	Y	Y The PI jointly ran the focus groups (conflict of interest?) Also trial recruited across urban-rural.	Y	Same study as above (Peters –Klimm 2009) but from perspective of doctors' assistants (nurses).
Lloyd-Williams 2005	Y	Y	Y	Y	Y	N	Not stated	Y	Y	Y	Y	Contributes to the field – little qualitative research in this area. Patients' +m nurses' views of a nurse-led HF clinic. On target for the review.
Young 2006	Y	Y	Y	Y	Y	N	Not stated	Y	Y	Only 5 elderly patients and split into two grps clinically	Y	Patients' perception of HF management (a community-based nursing intervention. Small sample (5). On target for the review.
Nasstrom 2013	Y	Y	Y	Y	Y	N	Not stated	Y	Y	Y	Y	Patients' description of HF "structured home-care" in Sweden

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Appendix 3 : Detailed CM-CHF qualitative study description table – 6 included studies

Patient only studies n=2					
Author Date Country Setting	Study design Sample size	Research question/ aim of study	Patient demographics Age Gender Ethnicity Disease status	Type of case management	Method of data collection Theoretical approach Method of data analysis
Young 2006 Canada Community-dwelling (recruited from community health centres)	Qualitative study Convenience sample 5 HF patients	‘What is the patients’ perception of care within a community based nursing intervention for HF patients?’	Age: range 72-97yrs Female: 40% Ethnicity: 3 Jewish 1 Ethiopian 1 Unknown Disease status: Gp 1 – patients with EF ≤35% who had frequent hospital visits. Gp 2 patients were followed by a community physician	HF-specific nursing care in the community based on: self-care including education, psycho-social issues, medication, nutrition advice, awareness of signs & symptoms of HF & co-ordination of health care services.	Semi-structured interviews. Grounded theory methodology. Content analysis

			regardless of EF.		
Nasstrom 2013 Sweden Community home care	Qualitative study 19 HF patients receiving structured home care at four different 'home care units'.	'to examine how HF patients receiving structured home care describe participation in their care.'	Age: range 63-90yrs Female: 32% Ethnicity: Not stated Disease status : All NYHA-class III except one patient was IV. Patients were receiving home care from between twice a day to once a month.	HF at Home Model. involving a multi-disciplinary team of doctors & nurses, HP educated in HF care, joint care plans/pathways, educational strategies for patients/carers, & increased accessibility to care.	Qualitative interviews.(no details) Theoretical approach: not stated Inductive approach using qualitative content analysis.
Patient & health professional studies n=2					
Lloyd-Williams [1447] 2005 UK	Nested qualitative study in RCT [abstract only published Lloyd Williams	'To explore patients' experience of attending a nurse-led PC HF clinic, & to explore	Patients Age: Mean age 74yrs (range 60-88yrs) Female: 13%	Nurse-led HF clinic in primary care	Semi-structured interviews conducted following schedule guidelines Theoretical approach: not stated Constant comparative analysis.

Primary care (no details available on recruitment to RCT abstract)	2004] Purposive sampling 15patients 4 practice nurses who delivered the pilot nurse- led clinics	nurses' experience of providing the clinic.'	Ethnicity: Not stated Disease status No detail on CHF status Mean *Jarman score (measure of deprivation) -0.3 (range -14,19)		
Close[95] 2013 UK Residential care home for older people in the community. (recruitment within home) HFinCH study	Nested qualitative study in RCT [EXTRA- Hancock] 17 patients 8 care home staff 5 GPs 3 HF nurses	'to examine experiences and expectations of clinicians, care home staff and residents in interpreting suspected symptoms of HF and deciding whether and how to intervene.'	Patients Age: 85.3 (5.1SD) (range 73-94yrs) Female: 52% Ethnicity: White British 100% Disease status LVSD 100% Care home staff 'a range of staff from qualified experienced nurses to newly recruited untrained care assistants'	A tailored, consultant-led management plan delivered by HF nurses. Intervention detailed in table X. 9 participants receiving HF (8 participants receiving usual care) service	Qualitative study using in-depth interviews with older people using transcendental phenomenological methodology Thematic analysis of transcribed participant interviews.

			<p>GPs came from 23 urban practices representing deprived, affluent & mixed populations staffed by a mix of GP partners & salaried GPs.</p> <p>HF nurses worked across several urban PCT boundaries & included experienced nurses with specialist qualifications & more junior staff working towards those qualifications.</p>		
Health professional only studies n=2					
Author	Study design	Research question/ aim of study	Patient demographics	Type of case management	Method of data collection
Date	Sample size		Age		Theoretical approach
Country			Gender		Method of data analysis
			Ethnicity		
			Disease status		

Setting			Health professional demographics Qualifications		
Peters-Klimm [881] 2009 Germany Primary care (GPs recruited through their practice) HICMAN trial	Nested qualitative study in RCT [4404] 24 GPs	‘To explore GPs’ perceptions of case management by doctors’ assistants, and its usefulness and benefit for patients and general practice.’	Age: mean 49.1yrs (SD 9.3) range 33-66yrs Female: 25% Ethnicity: Not stated Work experience: Mean 14.5yrs (SD9.2) (range 0-33yrs) 7 solo & 16 were group (≥4GPs) practices in a mixture of urban (8)suburban(5) &rural (10) areas	Multi-faceted CM approach based in German GP practices. Intervention detailed in table X	5 semi-structured focus groups of 90min (3-7 GPs in each) GPs with 6 structured questions. Four conducted by PI and a qualitative researcher and one by A HICMAN study nurse Theoretical approach: not stated Inductive content analysis using ATLAS.ti software.
Olbort[962] 2009	Nested qualitative study in RCT [4404]	‘To explore the views, concerns & experiences	Age: mean 35.9 (9.8SD) (range 21-54yrs) Female:	Multi-faceted CM approach based in German GP	Four focus groups conducted by PI and one other researcher The content of the focus groups followed the chronological course of the HICMAN trial.

Germany					
Primary care (DAs recruited through their practice)	27 doctors' assistants (DAs) (e.q. equivalent to a nursing role in UK).	of DAs of CM for HF patients while experiencing the new role of being a CM within the HICMAN trial.'	100% Ethnicity: Not stated. Work experience: Mean 11.6 (9.4SD) (range 0-34 ys.) Two were in third year of training. 8 solo & 17 were group (≥ 4 GPs) practices in a mixture of urban (8)suburban(4) &rural (13) areas Practice teams had a mean 4.5 DAs (SD2.4) (range 1- 11) 0-4 DAs were fulltime & 0-10 were part time employed	practices. Intervention detailed in table X	Theoretical approach: not stated Inductive content analysis using ATLAS.ti software.
HICMAN trial					

- Key: CM case management EF Ejection fraction, HF heart failure, HPs health professionals LVFS left ventricular systolic failure, PI principal investigator, PC primary care, SC secondary care,

*Jarman, B. (1983) Identification of underprivileged areas. *British Medical Journal* 1705 - 1709

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Reviewers' comment

Author's response to reviewers' comment

Reviewer ----Editor?	
1. The methods are poorly described. The 3 stage Thomas and Harden approach to qualitative thematic synthesis is not obvious. Thomas and Harden make it clear that findings can be located in any part of the primary report. Their approach is line by line coding onto the entire primary study. The 3 stages have not been well articulated. There is no clear progression from descriptive to analytical themes or how this was undertaken. Both referees feel that this is a superficial descriptive report with a very low level of synthesis. Please address.	With regard to the level of synthesis we have taken on board the reviewer's comments and with reference back to Thomas & Harden 2008 we have described the methods more fully on page 10 under the synthesis section. We have also added a schematic summary of the process (figure 2)
2. The Table (first table labelled 2) reporting the outcome of the quality appraisal process needs to move to an additional online only file.	CASP table is now relabelled Appendix 2 and this is also corrected in text as well
3. The appraisal assessments are not used to feed into the interpretation of findings. In the manuscript please say how you used these assessments when developing and interpreting findings.	We have addressed this and expanded on the quality issues with the results on p12,14 & 20 plus on p28 (discussion)
4. The discussion could more usefully report in detail the outcomes of the quant synthesis and say more about the mechanism for integrating the quant and qual synthesis (eg matrix, logic model etc).	The original aim of the project was to produce a mixed method review of CM for heart failure. However once we had identified both the intervention (quant) and qualitative papers we felt that although the intervention and patient/HP experiences complemented each other the main evidence from the intervention papers related to hospital-initiated CM as opposed to community-based CM. All the qualitative papers describe community-based CM. As such we decided as a team that we should analyse these data separately. In light of that we acknowledge that we have put too much emphasis on the link with the intervention paper and have edited the text appropriately on pages 6,7, 24, 26

22.12.17

5. Table 1 is not suitable for a print journal. It is too big with too much detail and white space. Please move this table to an additional online only file. Create a new succinct table for the print journal (max 1 page).	We have edited table one appropriately to fit one side of A4
6. There are two Table 2s. The second table only mentions descriptive themes and not analytical themes.	This has been addressed
Reviewer 1 comments:	
<p>7. Overall, the paper is somewhat challenging to read as it is more of a point by point type read versus a synthesis.</p> <p>8a. It would be helpful to readers to clearly identify the contexts of the case management as well as the components of case management that reduce admissions. (There is one paragraph in the discussion that does this to some degree on page 27 in the discussion.)</p> <p>Abstract The purpose is slightly different than the one in the body of the paper that refers to the context case management is delivered and the contribution of the different components to reducing admissions. Consider specifically citing the contexts throughout the manuscript. Some are discussed explicitly but most are implicit.</p>	<p>We have been back through text and addressed the style so as to not make it so 'point by point' and as a part of that we have removed excessive quotes but have put more context and detail (including CASP appraisal) in the narrative.</p> <p>We feel in part that our style came as a result of our thinking whilst writing the paper originally that we would keep the descriptive themes separate from the analytic themes, using the discussion to really explore the latter. Our reasoning was that the descriptive themes cover a breadth of issues which we felt were all important and we did not want to stint on them. Equally we feel we have been able to produce an in depth discussion this way. But we accept that this style probably does reflect a more traditional SR /quantitative approach to write up. In the case we feel this works</p>
<p>8b Background The background is quite brief and gaps in knowledge were not described. It would be helpful to readers to know more than this paper was an extension of the prior systematic review. There is conflicting evidence in the literature about the effectiveness of case management on reducing admissions as several reported no difference.</p>	We agree that the introduction/background are brief but were conscious of the word count and the readability of the paper. However we have discussed the greater evidence around CM in the discussion so we have moved some of that text forward into the introduction. We agree that there is conflicting evidence on CM and have quoted a SR that provides no convincing evidence for CM for the general older/COPD population (Purdy 2012)
9. The title is a little long and a little misleading because it has 2 methods	Original title:

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cited (systematic review AND qualitative synthesis). The authors followed the meta-synthesis procedures outlined by Thomas and Harden. Thomas and Harden refer to it as 'thematic synthesis of qualitative research' so consider using their terminology throughout (especially in the method/design section) and deleting systematic review from the title.

"Case management in the community for patients with heart failure and its relationship with unplanned hospital admissions: a systematic review and qualitative synthesis"

In view of the reviewers' comments we have changed the title to:

Community case management and unplanned hospital admissions in patients with heart failure: a systematic review and qualitative evidence synthesis"

this reduces words by 4 but hopefully still gets the message across.

We have left systematic review & qualitative evidence synthesis in the title as we believe we have used two methodologies

Systematic review methods as per Cochrane definition

"A systematic review attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question. Researchers conducting systematic reviews use explicit methods aimed at minimizing bias, in order to produce more reliable findings that can be used to inform decision making." Section 1.2 Cochrane handbook We have now referenced our systematic review methodology.

Whilst the searching for qualitative papers is not aimed at 'minimising bias' it is acknowledged that the actual process of searching for qualitative studies is akin to that of searching for a meta-analysis. (Thomas & Harden 2008) We are keen to distinguish between systematic review , and searching until saturation is achieved (Doyle 2003)

Our chosen approach is qualitative evidence synthesis by Thomas & Harden which have detailed and referenced (see point 10)

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<p>10. Page 9 - Design - I recommend deleting the words systematic review (Editor comment: Qualitative evidence synthesis or qualitative thematic synthesis is preferred - see also comments above about the title.)</p> <p>11. Page 9 - Quality appraisal. It would be helpful to readers to spell out the words for the acronym CASP and briefly describe the 10 quality questions it uses to assess the studies.</p> <p>12. On page 11, what constitutes 'good' quality for this paper?</p>	<p>See response to point 8.</p> <p>We have taken on the terminology of qualitative evidence synthesis</p> <p>Quality appraisal – CASP refers to Critical Appraisal Skills Programme. This has been changed. The CASP questions are detailed in the CASP checklist in appendix 2. Including these in the text would need quite a lot of words which we lose from presentation & discussion of themes.</p> <p>Thank you for picking this up. On reflection we think that describing the quality as good is not inadequate we have expanded this sentence and in addition we have extended the use of the critical appraisal as per point 3</p>
<p>13. Page 10 - The authors report coding based on 19 themes from a review paper. Is this referring to the systematic review alluded to in the introduction? I would not expect a review paper to have 'themes' so this confused me somewhat.</p> <p>(Editor note - not would this fit with the Thomas and Harden approach to inductive line by line coding. It would however fit with Framework synthesis).</p>	<p>No, the systematic review in the introduction is CM intervention review of which the citation is currently still blanked out. We have edited the text to make this clearer</p> <p>This same approach to identify qualitative studies via systematic review methods prior to synthesis has become an acceptable methodology in recent years and as a result qualitative themes are reported in the results section of a systematic review. This point is further explained by point 9. An example is</p> <p>Prostate cancer and supportive care: a systematic review and qualitative synthesis of men's experiences and unmet needs.Eur J Cancer Care (Engl). 2015 Sep;24(5):618-34. doi: 10.1111/ecc.12286. Epub 2015 Jan 29.</p> <p>Indeed the title of the Thomas and Harden methodology paper we quote is</p>

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	based on thematic synthesis within reviews.
14. Page 11 - Can you give a description of the problem with population sampling and appropriate involvement of study personnel? Although the study personnel issue is in the table, as written it leaves the reader wondering what you are talking about.	This has been addressed in point 3 & 12
15. Page 13 - You talk about the theme 'feeling cared for' was found in other studies, but only one is cited.	We have cited (Young <i>et al.</i> 2007, Nasstrom <i>et al.</i> 2015, Lloyd-Williams <i>et al.</i> 2005, Close <i>et al.</i> 2013) associated with this theme and presented quotes from two of the studies. This is also reflected in table 2 of the review descriptive themes.
16. Page 13 - Last sentence about reducing salt is a little awkward as written.	This has now been edited.
17. Page 15 - 3rd paragraph about information and decision making needs evidence to support it.	Five papers are referenced in relation to this theme and we have moved the Lloyd-Williams quote next to this paragraph (previously further down).
18. Page 17 - 1st paragraph on self-care and self-management. I would encourage you to review the work on self-care (self-care maintenance, self-care management, self-care confidence) by Dr. Barbara Riegel. She is one of the world's leading experts on self-care and she has published extensively on the topic in heart failure. Self-care is patient centered so the last line about what health professionals do is incorrect in my view.	Thank you for this comment on self-care/self-management We have updated our definition of the above using NHS relevant definitions we have also contextualised SC/SM within our representative quotes and discursive text
19. Page 18-19 is a series of 1 to 2 sentence "paragraphs". Can these be synthesized to improve the clarity and flow of ideas?	Addressed by points 7 and 8a

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Page 19 - HP needs to be spelled out before an acronym can be used.	HP refers to health professional, this has now been edited.
Page 23 - What exactly is the important angle of case management in the study by Close?	This study described an offsite HF service offered in care homes, So the important angle is that in all the other studies participants live at domestic home setting. We have edited the text to explain that and the synthesis does discuss the issue as to who takes ultimate responsibility for these patients.
Tables	See Point 5
Table 1 - Young citation - You refer to Ejection Fraction as Ej in one place and EF in another. EF is the most frequent acronym used in the literature so consider standardizing it in this paper.	We have edited table 1 to make it A4 size for inclusion in the main publication and as a result of that we have taken out clinical heart failure criteria so this acronyms are no longer part of the table.
What is meant by Jarman scores? I think this is unique to the UK so should be explained or deleted.	With the appendix 3 of the detailed table we have used EF and defined it and put very brief description in about Jarmon scale and referenced in key.
REVIEWER 2 COMMENTS: Whilst most of the data presented was in favour of the case management model, I think a particularly important point that was made by at least one responder that it is not always clear which health carer takes the lead in case management models, and there are sometimes tensions between GPs and heart failure nurses particularly. This was not picked up in the conclusion. Anecdotally in Australia, this is a problem for heart failure nurses, though GPs in the UK are more accustomed to working with nurses in the community so it may not be as big an issue there.	Table 1 although now slimmed down does outline the staff involved in the CM of patients in each study. Conflict between nurses and other staff came out in the Close study (HF nurses led by consultants) and the Peters-Klimm/Olbort study. These conflicts are described in the text and with the extra text on CASP checklist critique (point 3) we have commented on involvement of staff in the focus groups, so also adding context. However we agree with the reviewer and have added extra text in the discussion and the conclusion of the discussion plus we have added a phrase in the abstract to emphasise this point.
I note the updated literature search on the PRISMA flow diagram on 17 Feb 2017, however in the methods section this states that the updated search was undertaken in 17 Feb 2016.	Apologies for the confusion the update searches were in fact carried out on 16th Feb 2017. This has been corrected in abstract, main text and PRISMA flow chart

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	cover page
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	7-8
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix one
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9 (CASP)
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A



PRISMA 2009 Checklist

Page 1 of 2

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	9-10
RESULTS			
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	appendix 2
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10-11
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	11 and through out text
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	11-25
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	25
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	29-30
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	30
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	cover page



PRISMA 2009 Checklist

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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